STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED COMMISSION

ORAL TESTIMONY
PUBLIC HEARING REVIEW STANDARDS FOR SURGICAL SERVICES

Thursday, July 24, 2003
Michigan Library and Historical Center
702 West Kalamazoo
Lansing, Michigan

Approximately 29 people were in attendance.

(Proceedings scheduled to start at 10:30 a.m.; actual start time was 10:47 a.m.)

MS. ROGERS: It is 10:47, and we will start the hearing for Surgical Services. Good morning. My name is Brenda Rogers. I am Special Assistant to the Certificate of Need Commission from the Department of Community Health. Chairperson Renee Turner-Bailey has asked the Department to conduct today's hearing. We are here today to take testimony concerning potential language revisions to the Review Standards for Surgical Services. Please be sure that you have signed the sign-in log. Copies of the current CON Review Standards can be found on the table as well as cards to be completed if you wish to provide testimony. Please hand your card to me if you wish to speak.

Additionally, if you have written testimony and/or other documentation/data pertaining to any potential modifications to the CON Review Standards, please provide a copy as well. Further, please state and print your name and organization on the sign-in sheet located at the podium. As indicated on the card, written testimony and/or other documentation or other data may be provided to the Department through July 31st, 2003, at 5:00 p.m.

We will begin the hearing by taking testimony from those of you who wish to speak. The hearing will continue until all testimony has been given, at which time we will adjourn. Today is Thursday, July 24th, 2003, and we are now taking testimony. Dave Kaser, Covenant Medical Center, Saginaw.

MR. KASER: Good morning, Ms. Rogers. I'm here on behalf of Covenant which, for purposes of edification, is the result of the union of St. Luke's Hospital and Saginaw General, for purposes of the record. I'm an attorney with Miller, Canfield, Paddock and Stone, and we're general counsel to Covenant.

We're not here to oppose the standards; we're here to alert the Commission to a problem that exists within the standards and to ask that the standards be modified to address this problem. It's not a problem unique to Covenant, but as a matter of fact, I think as this morning's

comments will show, it's a problem that is really very common to those hospitals that have a broad range of surgical services.

Specifically, Covenant, as many other hospitals in the state, has -- performs a wide range of surgical procedures ranging from hip replacement and knee replacements to open-heart surgery to outpatient surgery, which, of course, is most frequently a much simpler and quicker procedure than those that I've identified within the hospital.

The difficulty comes when the State asks such hospitals to count up their utilization either by hours or by cases. The ORs within the hospitals that do the complicated, lengthy cases will likely qualify under the State's hourly standards but often can't qualify under the State's number of procedures per year standards. Likewise, the outpatient surgery rooms, outpatient surgical facilities, will perform a sufficient number of cases during a given period of time, but often the hours of operation will not be sufficient to meet the State's standards. Consequently Covenant requests that the standards be modified to, in effect, find ORs in compliance with the standards if ORs meet -- if each OR meets either the hourly standard or the procedures per year or per unit of time standard. We feel that this would fairly and properly reflect and accommodate both the planning system and the needs of the hospitals.

Later this morning you will hear comments offered by St. Joseph Mercy Hospital in Ann Arbor, and St. Joe will offer specific language which it will ask the Commission to consider and include in the standards. And with respect to the problem that I've mentioned this morning, Covenant will support that language. Thank you.

MS. ROGERS: Thank you. Forgive me if I mispronounce your name, but Robin Damschroder, St. Joe Mercy Health System.

MS. DAMSCHRODER: Hello. My name is Robin Damschroder. I'm the Chief Business Development Officer at St. Joseph Mercy Health System in Ann Arbor. We appreciate the opportunity to be able to discuss the Surgical Services Standard today and actually be able to propose changes.

Under the current CON standards ambulatory surgical services and main hospital operating rooms under the same hospital license and on the same campus are considered interchangeable. As a result, under the current CON Surgical Services Standards, hospitals must meet volume requirement utilizing uniform measures, cases or hours, as alluded to in the previous testimony.

The following two questions we believe need to be addressed when assessing the need to change the current CON Standards for Surgical Services. The first question: Are ASCs and main ORs that are covered under the same hospital license and located on the same campus truly interchangeable? We do not believe so. For ASC ORs to be truly interchangeable, they must be adjacent to a hospital's main OR and reside in the building that meets the State of Michigan's hospital building code. An ASC OR built on the same campus is often built in a separate and distinct location from its main OR. A separate and distinct ASC is not required to be built to the State of Michigan's hospital building code, nor is it usually equipped with the

necessary equipment and staffing resources required to perform the vast majority of inpatient cases.

In addition, the location is often not proximate to intensive care and nursing units, which might compromise patient care during transfers from a separate and distinct ASC. The distance also hinders the ease of transfer of limited specialty equipment.

Generally the ASC environments have afforded hospitals to improve care processes for these less intensive procedures while reducing associated costs by designing and equipping ASC ORs specifically for these types of procedures. The industry standard for a cost-per-square foot for an ASC OR versus a cost-per-square foot for a hospital's main OR is approximately 225 per square foot and $300 per square foot respectively. Therefore, a hospital ASC that is not constructed to the State of Michigan's hospital building code and adjacent to its main hospital's OR is not able to use its ORs interchangeably without compromising patient care or incurring additional costs.

The second question too, which the first testimony alluded to is, even if ASCs and main ORs are not interchangeable, why shouldn't they utilize the uniform measure to determine CON thresholds? The CON standards have recognized the impact of case complexity on utilization of facilities and equipment in several other procedural areas such as cath lab and MRI. Surgical cases present a similar situation as a case is not a case. And as alluded to before, an open-heart procedure averages about four hours, while the placement of tubes in a child's ears probably takes 10 to 15 minutes. ASC cases tend to have less variability in length of case, and thus casework is an appropriate measure; however, inpatient cases are significantly more complex, and case hours are generally accepted amongst most surgeons to be a measure for complexity.

This methodology would not require hospitals to incur additional administrative cost to track further relative value unit information that is currently performed for MRI; however, we do recognize that hospitals have elected to place their ASCs and main ORs in adjacent space, thus creating flexibility those hospitals without adjacent ORs don't have. We strongly believe that it is important that changes to the CON Surgical Services criteria clearly delineate when ASCs and main ORs are under the same hospital license, are not interchangeable and thus would not be required to use the same uniform measure of volume.

We would be recommending amending Section 3 of the standard to include a subset (d) that might read:

"In a hospital site which has, one, inpatient and outpatient operating rooms which are not adjacent, and, two, also are built to different hospital building code requirements, surgical volumes shall be measured in terms of hours for inpatient operating rooms and in terms of cases for outpatient operating rooms. Documentation of building code status must be provided via JCAHO required statement of condition documentation or other accrediting body of evidence of building code adherence, and floor plans shall be used to verify operating room adjacency." Thank you for your consideration.

MS. ROGERS: Thank you. Phyllis Adams, Borgess Health Alliance and Borgess Medical Center.

MS. ADAMS: Good morning. My name is Phyllis Adams. I'm a healthcare attorney with Dykema Gossett PLLC. Borgess Health Alliance, including Borgess Medical Center, requested I present the following testimony today with respect to the Michigan CON Review Standards for Surgical Services.

Borgess supports continued regulation of surgical services under the Michigan CON program; however, Borgess proposes several revisions to the current CON Review Standards to address the following issues: One, Borgess requests that a new provision be added to the definitions in Section 2 of the standards to actually define "surgical procedure."

Currently, as a matter of practice, the Michigan Department of Community Health determines whether a procedure qualifies as a surgical procedure based on whether the procedure is eligible for Medicare reimbursement as an inpatient or outpatient hospital or ASC procedure. Given that the definition of "surgical procedure" is critical to a determination of whether CON minimum volumes are met, it would be helpful to incorporate this practical method of defining "surgical procedure" into the actual CON Review Standards. We note that certain procedures would clearly constitute surgery but may not be a Medicare covered benefit. These procedures may not appear on any list of reimbursable procedures published by the Medicare program. Thus the proposed language also includes a provision which would look to the Michigan Public Health Code and applicable Health Facility Licensure Regulations under these circumstances. This would be applicable for certain cases such as plastic surgery.

Second, Borgess proposes revisions to Sections 3(1) and 3(3) of the standards to specifically recognize that hospitals which offer both inpatient and outpatient surgery services under a single license should be permitted to count surgical volume using hours of use for inpatient procedures and surgical cases for outpatient procedures under a so-called mixed methodology.

Hospitals are currently penalized by the Department's interpretation of the standards which requires hospitals to elect only a single methodology for computing surgical volume, meaning either hours of use or surgical cases but not both. This approach results in significant under reporting of hospital surgical volume and discriminates against hospitals in favor of free-standing surgical outpatient facilities. We believe that this is an overly technical interpretation of the standards. Hospitals should have the flexibility to count their surgical volume using hours or cases or both depending on the type of surgery services that are provided at that facility.

The current interpretation ignores the distinctions between the types of cases performed on an inpatient versus outpatient basis as well as scheduling and procedure time differences for these fundamentally different types of surgical services. For example, as other commenters have indicated already, inpatient surgery procedures may involve an orthopedic or vascular surgery case that may require up to eight hours of surgery time. On the other hand, in the outpatient area of the facility there continued to be 45-minute to 1-hour cases that are going

on all the time. If the hospital is required to count all of their surgery volume using one method or the other, it's seriously under counting the utilization of either the inpatient or the outpatient service or maybe even both.

Hospitals should also not have to separately license and certify their outpatient surgery departments as free-standing surgical outpatient facilities to be able to count their outpatient volumes separately using surgical cases.

We have provided some sample language, or will, to the Department which includes some suggested language revisions to address this issue, but we're not tied to this particular language. We noted the comments of the other speakers and would support any reasonable language that would address this issue.

Third, Borgess proposes that Section 3 subparagraph 2 of the existing Surgical Standards be revised with respect to which operating rooms at a surgical facility are counted for purposes of compliance with CON minimum volume requirements. Currently there's no full or partial exclusion from the total operating room count for hospitals which operate an open-heart surgery service and maintain one or more operating rooms exclusively or partially for emergency open-heart surgery cases. Hospitals offering open-heart surgery are not given any credit for the fact that these operating rooms are not routinely scheduled with general surgery cases in order to make this capacity available for those patients in need of cardiac surgery.

The proposed language mirrors that which appears currently in the CON standards to permit a full or partial credit for an operating room used for burn care or trauma care. This change to the CON standards is long overdue. The current surgical standards penalize those hospitals with specialized surgical capacities and programs.

Finally, Borgess proposes that an entity seeking to initiate a new surgical service could not use physician commitments which include surgical procedures performed in a physician office setting. This restriction would apply even if such procedures appear on the list of surgical procedures which would be reimbursed by Medicare in a hospital outpatient or ASC setting. We believe that on a historical basis, the fact that these procedures were actually performed in a physician office setting demonstrates that these procedures are not appropriate FSOF or ASC volume based on Michigan licensure requirements for free-standing surgical outpatient facilities. Thank you.

MS. ROGERS: Thank you. Maureen Halligan, Genesys.

MS. HALLIGAN: Good morning. My name is Maureen Halligan. I'm Director of Strategic Planning for Genesys Health System, and I thank you for the opportunity this morning to speak on Surgical Standards.

First of all I'd like to say that we support the comments previously presented by Phyllis Adams on behalf of Borgess. We're in agreement with those recommended changes. We would also like to suggest a recommended change to the definition of "hours of use" in the Surgical Standards that would include room setup and room cleanup time rather than the

current definition, which is patient in room to patient out of the room. Those rooms have to be set up, and when you have a lot of really quick cases, that eats up a lot of available OR time. And, of course, they have to be cleaned up in between cases. So all of that adds into the amount of time that your ORs are not in use. But we're not allowed to count that in the hours of use, and that makes it very difficult for many hospitals to meet that minimum volume of hours. So just as a quick summary, we'd like to recommend a change to the definition of "hours of use" to include room setup and cleanup. Thank you.

MS. ROGERS: Thank you. Robert Meeker, Spectrum Health.

MR. MEEKER: I'm Bob Meeker from Spectrum Health in Grand Rapids. And I have not been deputized by the Alliance for Health this time, so I'm speaking only for Spectrum Health. Basically we have very few comments suggesting the need for changes in the CON Review Standards for Surgical Services. We think that these standards have withstood the test of time, that the populace of the State of Michigan has been well served using these standards as guidelines and that the numbers, the requirements of either 1,200 cases or 1,600 or 1,800 hours are fair.

We have two relatively minor comments. Maybe one is not so relatively minor, but picking up on the comments previously about the definition of "surgical case," you know, the current definition is very vague. And I know that the reviewers at the Department of Community Health have labored under that for a long time and, therefore, have been -- they've had no choice but to look for other guidelines even though they are not ensconced in the standards. You know, I think that clearly the standards or the definition of "surgical case" could be tightened. You know there are a number of -- there are number of definitions out there, whether it's the American College of Surgeons or from CMS, but certainly components like "should be invasive," perhaps, "should require anesthesia either local or general," and "it involves a recovery period," those I think are -- might be a good starting point to then discuss, you know, how those might need to be modified.

Secondly, and this is very kind of technical, but in reviewing these standards with our in-house experts, we discovered that there was a section that was not clear. It was clear to me because I've used it before, but when some of the other folks said, "Well, it's Section 9(d) sub (iii)." It says that, "Surgical services performing outpatient surgery shall have policy which allow for hospitalization of patients when necessary."

One of our -- the smaller hospitals in Spectrum Health said -- and it goes on to say that they have to be within 30 minutes or 30 miles and so forth. One of the smaller hospitals in our system said, "Well, we don't have such a transfer agreement because we're a hospital." But in my -- my reading of it is that "surgical facilities" here was really referring to outpatient surgical facilities or AFCs and FSOFs. So I think that this section would be much clearer in the Project Delivery Requirements if wherever it says "surgical facilities" was just replaced in that section with "AFCs" and "FSOFs," which are defined elsewhere in the standards. I don't think it's caused a problem other than it's just confusing.

MS. ROGERS: Thank you. Barbara Jackson, Economic Alliance of Michigan.

MS. JACKSON: Good morning again. I'm still Barbara Jackson. I'm still Regulatory Director of EAM I think. At this time EAM has no official position on surgical service standards; however, we do understand the overall significance in updating these standards to better address facility efficiency and compliance issues. We applaud St. Joe Mercy hospital in Ann Arbor and Covenant and Borgess and all the other folks who've come forward to draft language that better reflects current surgical service needs and only hope that other hospitals will also join forces. EAM feels that a key provision for any suggested revision to these standards should incorporate comprehensive language that reflects the needs of the facilities to better effect the operational efficiencies and facility compliance but is distinctive and easily enforced and interpreted by MDCH staff. Thank you.

MS. ROGERS: Thank you. Does anyone else wish to provide testimony regarding surgical services? Hearing none, this hearing is adjourned at 11:12. Thank you.

(Proceedings concluded at approximately 11:12 a.m.)